

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE: :
Fosamax Products Liability Litigation : 1:06-md-1789 (JFK)
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This Document Relates to: :

Cook, Jessie v. Merck & Co., Inc., : **Memorandum Opinion**
Case No.: 1:08-cv-3857-JFK : **& Order**
:

Carpenter, Brenda v. Merck & Co., Inc., :
Case No.: 1:07-cv-3464-JFK :

Avery, Linda v. Merck & Co., Inc., :
Case No.: 1:07-cv-8033-JFK :

Quarles, Rebecca v. Merck & Co., Inc., :
Case No.: 1:07-cv-11334-JFK :

Monday, Marlies v. Merck & Co., Inc., :
Case No.: 1:07-cv-6752-JFK :

Johnson, Janice v. Merck & Co., Inc., :
Case No.: 1:07-cv-01421-JFK :

White, Kenneth v. Merck & Co., Inc., :
Case No.: 1:07-cv-01319-JFK :

Boniol, Sandra v. Merck & Co., Inc., :
Case No.: 1:06-cv-12968 :

Beechler, Marianne v. Merck & Co., :
Inc., Case No.: 1:08-cv-09147-JFK :
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Burns, Charlette et al. v. Merck & Co., :
Inc., Case No.: 1:08-cv-01803-JFK :

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Barr, William v. Merck & Co., Inc., :
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Inc., Case No.: 1:07-cv-7220-JFK :

Burnette, Virginia v. Merck & Co.,
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Giebel, Kathleen v. Merck & Co., Inc., :
Case No.: 1:07-cv-9880-JFK

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JOHN F. KEENAN, United States District Judge:

Currently pending in this multi-district litigation is Defendant Merck & Co., Inc.'s ("Merck") motion for summary judgment filed in 24 cases. Plaintiff in each case has submitted a profile form disclosing that he or she took Fosamax for fewer than three years. Merck seeks to exclude expert testimony that Fosamax can cause osteonecrosis of the jaw

("ONJ") before three years of continuous use. Merck further contends that the inadmissibility of general causation testimony on this so-called "three-year issue" entitles Merck to summary judgment against these plaintiffs.

For the reasons below, testimony by two of plaintiff's experts is admissible in these cases and sufficient to create a genuine issue of fact for trial. Therefore, Merck's motion for summary judgment is denied.

I. BACKGROUND

A. Factual Background¹

The Court assumes familiarity with its decision dated July 27, 2009 (the "July 27, 2009 Opinion"), which admitted the testimony of three of plaintiffs' general causation experts, Dr. Robert E. Marx, Dr. Alastair Goss, and Dr. John Hellstein. In re Fosamax Prods. Liab. Litig., -- F. Supp. 2d ---, 2009 WL 2222910, at *8-19 (S.D.N.Y. July 27, 2009). In that opinion, the Court reserved decision on the admissibility of the experts' opinions relating to the three-year issue. Id. at *31.

1. Dr. Marx

Throughout 2007 and 2008, Dr. Marx published in the medical and dental literature that there is minimal or no risk of ONJ

¹ The following facts are drawn from the parties' Local Rule 56.1 statements, the declarations and exhibits submitted with this motion and with the Daubert motions filed on May 8, 2009, and the testimony given at hearings conducted on July 9 and 16, 2009.

before three continuous years of oral bisphosphonate use.² This "3-year threshold," as he described it, was based on his clinical experience treating patients with ONJ, his measurement of their bone turnover levels, and his theory about the slow accumulation of oral bisphosphonate in the bone. (See, e.g.,

² See Def.'s Mem. in Support of Motion for Summ. J. ("Def.'s Mem.") Ex. 31 (Marx, Oral & Intravenous Bisphosphonate-Induced Osteonecrosis of the Jaws, 82, 87 (Quintessence Publ. 2007) ("Marx Book")) (stating that "regular use of an oral bisphosphonate for a period of less than 3 years suggests minimal or no risk" and that "the risk of developing exposed bone does not become significant until 3 years of continuous use"); Ex. 29 (Sawatari & Marx, Bisphosphonates and Bisphosphonate Induced Osteonecrosis, Oral Maxillofacial Surg Clin N Am (2007) 487, 490) (stating that "3 years or 156 continuous weekly doses . . . are required to place patients who take Fosamax or Actonel into the risk range for BIONJ [bisphosphonate-induced ONJ]"); Ex. 30 (Marx, Editorial, Bisphosphonate-Induced Osteonecrosis of the Jaws: A Challenge, a Responsibility, and an Opportunity, 28 Int'l J. Periodontal Restorative Dentistry 5 (2008) (stating that "the critical difference in oral BIONJ risk is that it does not begin until after about 3 years of oral bisphosphonate use"); Def.'s Reply in Support of Motion for Summ. J. Ex. 1 (Marx, Interview, Conversations With Oncology Investigators Bridging The Gap Between Research And Patient Care, 6 Breast Cancer Update 31-37 (2007)) (stating that "[t]he pathophysiology is directly related to dose and time of exposure to the BP," and "[w]e found that you don't have a risk for ONJ until you've been on an oral BP for three years, and most cases occur with five or more years of therapy. So it's related to dose accumulation.")); 07/09/2009 Hrg. DX J (citing Marx et al., Osteonecrosis in the Jaws of Patients Who Are Using Oral Bisphosphonates to Treat Osteoporosis, Int. J. Oral Maxillofac. Implants, 2007 Nov;19(4):487-98, 490 (stating that "the risk for developing exposed bone is negligible with oral bisphosphonate exposure of less than three years"); Marx et al., Oral Bisphosphonate-Induced Osteonecrosis: Risk Factors, Prediction of Risk Using Serum CTX Testing, Prevention, and Treatment, J. Oral Maxillofac Surg. 2007 Dec., 65(12):2397-2410 (stating that "patients taking oral bisphosphonates for less than 3 years have little risk for ONJ"); Marx, Abstract, Prevention and Treatment of Oral & Intravenous Bisphosphonate Induced Osteonecrosis of the Jaws, J Oral Maxillofac. Surg., 2008 Aug; 66(8 Suppl.): 140-41 (stating that "patients requiring elective oral surgical procedures who have taken an oral bisphosphonate for less than three years have no perceivable additional risk beyond the sex and age matched general population"))).

Marx Book, supra n.1, at 79-81, 87.) Dr. Marx recognized that co-morbidities and concomitant treatments, in particular steroid therapy, can hasten the development of ONJ. (Id. at 79.) His overall message, however, was that the risk did not begin or become significant until three years of use, so it generally was safe to perform invasive dental procedures before then.

Until recently, Dr. Marx's testimony in litigation aligned with his published views on this subject. In three depositions, the first taken in May 2007 and the latest in August 2008, he offered expert testimony that there was no significant risk of ONJ before three years of oral bisphosphonate use.³

On January 23, 2009, Dr. Marx submitted an expert report expressing a different opinion on the three-year issue. (Marx

³ See Def.'s Mem. Ex. 32 (05/15/07 Marx Dep. Tr.) at 48 (stating that, with "the oral bisphosphonates, due to the delayed absorption or decreased absorption accumulates in bone much slower. Our studies have indicated clearly that it takes three years of exposure with Fosamax, for instance, to put a person at risk. . . ."); Ex. 27 (06/01/07 Robert E. Marx Dep. Tr.) at 77 (stating that his "oral bisphosphonate article with CTX testing, indicates that - and other articles confirm this, too - that within three years of taking Fosamax, there is not a significant risk with dental procedures" and that "the toxicity buildup in an accumulation of bone . . . begins around three years and becomes significant around five"); id. at 80 (agreeing that "there is no significant risk of osteonecrosis of the jaw from Fosamax until after three years of continuous use" and that the risk is "small, if insignificant"); id. at 221 (agreeing that he "see[s] no risk to [Fosamax] users of less than three years"); Ex. 33 (08/04/2008 Marx Dep. Tr.) at 63-64 (testifying that "with three years or more of alendronate, which is Fosamax, we have seen associated with delayed healing and at some times frank ONJ" and that this risk "begin[s] with three years. Then, as you go more than three years, the risk factors increase more and more, and the CTX drops more and more").

Report ¶¶ 43-35.) In the report, he acknowledges his previous opinion that a person generally is not at significant risk of ONJ until three years of Fosamax use. (Id. ¶ 43.) He explains that this opinion was based on the patient population he had seen, but that it is "very likely that other practitioners see it at earlier times." (Id.) He now asserts that "No general time frame can be reached related to developing BIONJ applicable to all patients at or before 36 months of oral bisphosphonate use because of individual issues such as the number of dosings, prescription compliance, co-medications and co-morbidities in these patients." (Id. ¶ 44.) His report does not describe the risk before three years as minimal or insignificant.

On July 9, 2009, the Court held a Daubert hearing to evaluate the reliability of Dr. Marx's current opinion on this issue. At the hearing, he explained that his prior opinion was influenced by what he called "referral bias" because his clinic generally receives patients with more advanced cases of ONJ. (07/09/2009 Hrg. Tr. at 95-96, 103.) Several factors led him to change his opinion sometime in early 2008, although he could not further specify when. First, he realized that his three-year threshold was based on an erroneous assumption that his patients had taken oral bisphosphonates continuously and as directed. (Id. at 102-03, 110, 113-14, 140-41). After re-questioning some patients, he discovered that several had not complied with their

prescriptions.⁴ (Id. at 145-48.) Therefore, according to Dr. Marx, a few patients actually developed ONJ before receiving a full three years' dose. (Id. at 110, 113-14.)

Second, Dr. Marx was persuaded by internal Merck emails produced in discovery analyzing spontaneous ONJ reports Merck has received, which he reviewed in early or mid-2008 (07/09/2009 Hrg. Tr. at 100-01, 136; Marx Report ¶ 45.) A June 2005 email from the director of Merck's Clinical Risk Management and Safety Surveillance noted that there was "a range of durations reported," with a median of four years and a minimum of eight months. (Pl.'s Mem. in Opp'n to Summ. J. ("Pl.'s Mem.") Ex. 1.0136.) The email concluded, "If their implication is that very long treatment makes for more likely occurrence, our data do not currently support that hypothesis." (Id.) A November 2006 email revealed that 31 of the 71 reports adjudicated by Merck to be highly likely cases of ONJ involved less than or equal to three years of Fosamax use. (Pl.'s Mem. Ex. 1.0185.)

In addition, Dr. Marx explained that his change of opinion was influenced by prevalence studies published by Dr. Goss in 2007 (the "Australian study") and by the University of Southern California in January 2009 (the "USC study"). (07/09/2009 Hrg.

⁴ On cross-examination, defense counsel established that Dr. Marx was aware of this back in 2007, well before his change of opinion, when he published that "patients often do not take the medication as directed, leading to variable absorption rates" (07/09/09 Hrg. Tr. at 141.)

Tr. at 105-06, 117-18.) The Australian study, a survey of oral maxillofacial surgeons sponsored by Australia's health authority, found a two-year median duration of Fosamax use prior to ONJ onset in 30 cases. (Pl.'s Mem. Ex. 2.0348 at 419). The USC study found that two of nine reported ONJ cases occurred within one year of Fosamax use. (Id. Ex. 2.0805.) It concluded that these findings "indicate that even short-term oral use of alendronate led to ONJ in a subset of patients after certain dental procedures were performed." (Id.)

Dr. Marx has not written his current opinion on the three-year issue anywhere except in his expert report. (07/09/2009 Hrg. Tr. at 103, 128, 133.) He recognizes that dentists still may be relying on his published advice and performing dental surgeries because they believe there is no risk before three years. (Id. at 128.) He has not published anything to retract or correct his prior views, but intends to do so once the data is gathered and analyzed. (Id. at 128, 134.) He would have liked to publish an article based on Merck's internal adverse event data, but was prohibited from doing so by a confidentiality order. (Id. at 156.)

Dr. Marx accepts responsibility that his "initial three year rule" may have contributed to the misinformation about ONJ that is prevalent in the literature. (Id. at 157.) His earlier articles were meant to help his colleagues treat or prevent an

emerging disease. (Id.) They were "not designed for such scrutiny we have by a Court about dates and such." (Id.)

2. Dr. Goss

Dr. Goss has researched and published on bisphosphonate-associated ONJ for several years. There is no indication that he has ever endorsed Dr. Marx's three-year threshold. In his expert report, Dr. Goss acknowledges that the time to onset of ONJ from the commencement of oral bisphosphonates is usually greater than three years. (Goss Report ¶ 14.) He asserts, however, that "there exist numerous instances of the onset being less, including some markedly less than that time period." (Id.) He concludes that "one cannot set a time-to-onset threshold to definitively rule out a subset of the population as being at risk for developing osteonecrosis of the jaw secondary to Fosamax use." (Id.)

At his trial deposition, Dr. Goss testified that there is no safe period, apart from the first month or two, before which an oral bisphosphonate user is not at risk for ONJ. (3/27/09 Goss Dep. Tr. at 110-11.) On direct examination, he cited the following evidence to support this opinion: his clinical experience, in which he has observed ONJ develop within twelve weeks of Fosamax treatment (id. at 111-12); the results of his survey, which found the median duration to be two years (id. at

112);⁵ the internal Merck emails and data discussed above, which he believes "show[] that clearly ONJ can occur at any time period" (id. at 113-117); his research measuring bone turnover markers, which shows that bone turnover is completely suppressed within six to eight weeks after beginning Fosamax treatment (id. at 118-119); and the USC study, reporting two cases of ONJ that developed within one year of Fosamax treatment. (Id. at 119-20.) Defense counsel did not cross-examine Dr. Goss about his views on this issue.

3. Dr. Hellstein

Dr. Hellstein has published several articles on the link between oral bisphosphonates and ONJ. There is no indication that he ever subscribed to the three-year threshold. In his expert report, he opines that oral bisphosphonates cause ONJ and describes the alleged causal mechanism. At his deposition, he testified that "there is no magic time line . . . I don't think we can put a line on things." (Pl.'s Mem. Ex. 9 at 119.) At a Daubert hearing held on July 16, 2009, Dr. Hellstein gave the following testimony on this issue:

I believe that the duration of the bisphosphonate being used makes a difference and that essentially it becomes a sliding scale. The more that is taken, the more risk there is. And that individual patients also are variable and that there is no line that can be drawn that you could say absolutely there is no risk.

⁵ Dr. Goss presented his survey results to Merck at a September 2006 meeting to which he was invited as an expert on the topic of ONJ.

(7/16/2009 Hrg. Tr at 331-32.)⁶

B. Procedural History

Around May 2008, relying on Dr. Marx's statements, Merck sought to obtain summary judgment in a case involving less than three years of Fosamax use. On October 24, 2008, the Court issued a case management order deferring all summary judgment motions until after the completion of common-issue fact and expert discovery. Case-specific discovery, including the designation of specific causation experts, has not begun yet.

On May 8, 2009, pursuant to the case management order, Merck filed the instant motion seeking summary judgment against the above-captioned plaintiffs, all of whom had submitted a profile form disclosing less than three years of Fosamax use. On June 8, 2009, the Plaintiffs Steering Committee (the "PSC") filed a brief opposing the motion on behalf of the affected plaintiffs.⁷

⁶ Merck objected to this testimony on the ground that it is not contained in Dr. Hellstein's expert report. This objection is overruled. The report's discussion of general causation fairly encompasses testimony on when the risk begins. Even if it did not, Merck has had two opportunities to cross-examine Dr. Hellstein on this issue, curing any possible prejudice from insufficient disclosure.

⁷ Several of the plaintiffs have submitted opposition briefs on their own behalves. The Court finds it unnecessary to consider their arguments for them to prevail on the motion.

II. DISCUSSION

Merck argues that it is entitled to judgment as a matter of law because plaintiffs offer no admissible expert testimony that Fosamax can cause ONJ before three years of continuous use.

A. Applicable Law

A district court may grant summary judgment only "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). This standard requires the court to "resolve all ambiguities, and credit all factual inferences that could rationally be drawn, in favor of the party opposing summary judgment." Brown v. Henderson, 257 F.3d 246, 251 (2d Cir. 2001) (internal quotation marks and citation omitted). The moving party bears the burden of demonstrating that summary judgment is appropriate. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). If the moving party meets that burden, the opposing party must produce specific evidence demonstrating the existence of a genuine dispute of material fact. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

In deciding a motion for summary judgment, a district court may only consider admissible evidence. Jaramillo v. Weyerhaeuser Co., 536 F.3d 140, 145 (2d Cir. 2008); Raskin v. Wyatt Co., 125 F.3d 55, 66 (2d Cir. 1997); Tamarin v. Adam Caterers, Inc., 13

F.3d 51, 53 (2d Cir. 1993). The admissibility of expert testimony is governed by Federal Rule of Evidence 702, as interpreted by Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993). Rule 702's requirements are fully described in the July 29, 2009 Opinion. See In re Fosamax, 2009 WL 2222910, at *4-6. Essentially, the district court must serve as a gatekeeper to ensure that the testimony is reliable. Id.

The standard of admissibility under Rule 702 is the same at the summary judgment stage as it is at trial. See Gen. Elec. Co. v. Joiner, 522 U.S. 136, 143 (1997) ("On a motion for summary judgment, disputed issues of fact are resolved against the moving party . . . but the question of admissibility of expert testimony is not such an issue of fact."); Raskin, 125 F.3d at 66. If proffered expert testimony is found inadmissible, the district court must make the summary judgment determination on a record that does not include that evidence. See Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 268 (2d Cir. 2002) (affirming grant of summary judgment after exclusion of expert testimony because plaintiff failed to present any admissible evidence in support of his theory of causation); Brooks v. Outboard Marine Corp., 234 F.3d 89, 92 (2d Cir. 2000) (affirming grant of summary judgment where plaintiff had no expert evidence to support a finding of causation under his design defect theory

after his expert was excluded). If the testimony is admissible, the court is "bound to consider the evidence in the light most favorable to plaintiff" in deciding the summary judgment motion. Amorgianos, 303 F.3d at 268. (quoting In re Joint Eastern & Southern Dist. Asbestos Litig., 52 F.3d 1124, 1135 (2d Cir. 1995)). The "Daubert gatekeeping role does not permit the district court, in ruling on evidentiary sufficiency, to reject admissible expert testimony." Id.

B. Admissibility

In the July 27, 2009 Opinion, the Court found the general causation testimony of Dr. Marx, Dr. Goss, and Dr. Hellstein sufficiently reliable because it was supported by, among other things, clinical experience, biologic plausibility, peer-reviewed publications and independent research, case reports and adjudicated adverse event reports, and prevalence studies. In re Fosamax, 2009 WL 2222910, at *8-19. As noted above, the Court reserved decision on the admissibility of their testimony on whether Fosamax can cause ONJ before three years of continuous use. Id. at *31.

1. Dr. Marx

Several of the reliability factors justifying the admission of Dr. Marx's general causation testimony do not support admission in cases involving less than three years of use. With

respect to his clinical experience, nearly all of the fifty ONJ cases he has seen in oral bisphosphonate patients developed after three years of use. He now dismisses this observation as a product of referral bias and an inaccurate assumption about dose accumulation. For years, however, he presented his clinical findings to the medical and dental communities as evidence of a "3-year threshold." He published that there is "minimal or no risk" before three years, that "three years are required to place patients who take Fosamax or Actonel into the risk range," that "oral BIONJ risk . . . does not begin until after about 3 years of oral bisphosphonate use," and that "we found that you don't have a risk for ONJ until you've been on an oral BP for three years." See supra note 1.

Dr. Marx admits that the only place he has written his new opinion on this subject is in his expert report. Although he claims that he changed his opinion about a year and a half ago, sometime in early 2008, he has not published anything, not even a letter to the editor, to retract or correct his prior views. He has not done so despite recognizing that his "initial three-year rule" has contributed to the misinformation about ONJ that is prevalent in the literature, and that some practitioners may be performing surgery in reliance on his advice that there is no significant risk before three years of use. That he has not yet presented his new opinion for publication suggests that he does

not hold it to the same degree of scientific certainty.

Furthermore, the timing of Dr. Marx's change of opinion raises a question as to whether it was made independent of litigation concerns. His three-year threshold became a litigation issue around May 2008, when Merck first sought summary judgment based on his prior views. At the Daubert hearing, Dr. Marx testified on direct that he changed his opinion "probably in early 2008." (07/09/2009 Hrg. Tr. at 97). It was then pointed out to him that, in August 2008, he testified that the risk "begin[s] with three years." (Id. at 102, 123-24.) When pressed about this on cross-examination, he replied that "changing your mind takes a little bit of time," so, for the purpose of that sworn testimony, he "was sticking with [his] original thought process" on the three-year issue. (Id. at 124.) Later in the hearing, he was confronted with an abstract he wrote that was published in October 2008. In the abstract, he stated that "From our experience, patients requiring elective oral surgical procedures who have taken an oral bisphosphonate for less than three years have no perceivable additional risk beyond the sex and age matched general population." (Id. at 126-27.⁸ Dr. Marx did not explain

⁸ The abstract was published in connection with the annual meeting of the American Association of Oral Maxillofacial Surgery ("AAOMS"). Dr. Marx explained that he wrote and submitted the abstract more than a year before publication and that the organization would not have permitted changes. (Id. at 127-30.) When asked whether the

what changed between August or October 2008 and January 2009, when he submitted his expert report.

The PSC argues that Dr. Marx never presented the three-year threshold as absolute. Rather, he usually qualified it by stating that, before three years, there may be a minimal or insignificant risk, or that "most all" dental procedures could be performed safely. Yet his expert report does not speak of a minimal or insignificant risk. Instead, he seeks to offer a stronger opinion that is inconsistent with the one he presented to the medical and dental community for several years.

The PSC also points out that scientific knowledge is always evolving, especially knowledge about new adverse drug reactions such as bisphosphonate-associated ONJ. This fact does not permit an expert to offer scientific opinions without demonstrating a reasonable degree of reliability and certainty. "[T]here are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly." See Daubert, 509 U.S. at 596-97.

organization really would prohibit the correction of an important error that could mislead surgeons, Dr. Marx conceded that he did not know what the organization would have done because he did not contact it to notify it of the error. (Id. at 130.) He claims that he corrected the error during his lecture at the AAOMS meeting. (Id.)

On balance, the Court finds that the PSC has failed to show that Dr. Marx's new opinion on the three-year issue is sufficiently reliable to be admitted under Rule 702.

2. The Other Experts

The Court finds no basis to so restrict Dr. Goss's or Dr. Hellstein's general causation testimony. Nothing in the record suggests that either expert previously endorsed the view that the risk of ONJ is minimal or insignificant before three years of oral bisphosphonate use. Their opinion that there is risk before three years is specifically supported by Dr. Goss's Australian study, the USC study, and Merck's internal analysis of adjudicated adverse event reports. Therefore, Merck's motion to exclude their general causation testimony from cases involving less than three years of Fosamax use is denied.

C. Sufficiency

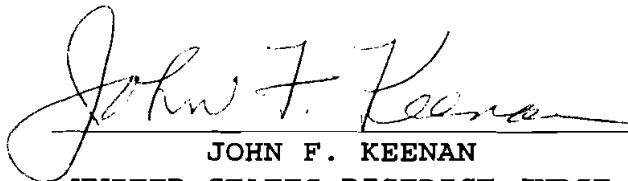
Viewing the evidence in a light most favorable to plaintiffs, a rational jury could conclude on the basis of the testimony of Dr. Goss and Dr. Hellstein, and the evidence upon which they rely, that Fosamax can cause ONJ before three years of use. In addition, once case-specific discovery begins, each plaintiff will have an opportunity to designate a specific causation expert to testify that Fosamax caused him or her to develop ONJ. Such testimony, if admissible, may be sufficient by itself to make causation a genuine issue of fact for trial.

CONCLUSION

Accordingly, Merck's motion for summary judgment (doc. no. 619 in 06-md-1789) is DENIED.

SO ORDERED.

Dated: New York, New York
September 8, 2009


JOHN F. KEENAN
UNITED STATES DISTRICT JUDGE